REMARKS

Responsive to the final Office Action mailed 13 April 2010 and with an extension of time to reply of two (2) months, the present paper is timely filed contemporaneously with a Request for Continuing Examination under 37 C.F.R. § 114 on or before 13 September 2010. A Petition for Extension of Time under 37 C.F.R. § 1.136 and the required fee are also filed herewith.

By the present paper, claims 3 - 14, 16 - 26, and 31 - 36 are cancelled without prejudice or disclaimer of subject matter therein, and new claims 37 - 92 are presented. The additional claim fees are paid herewith. Upon entry of the Request for Continuing Examination, claims 37 - 92 will be in the Application.

An Information Disclosure Statement is filed herewith. The references listed on accompanying form PTO/SB/08a were cited by the Japanese Patent Office in the case of corresponding Japanese Application 2006-500243.

Entry of the Request for Continuing Examination, entry of the new claims, and reconsideration of the Application are respectfully requested.

The New Claims

New claims 37 - 92 replace cancelled claims 3 - 14, 16 - 26, and 31 - 36.

Claim 36, the only independent claim that was under examination, was previously presented in response to an Examiner's interview on 18 November 2009. Support for claim 36, now cancelled, was described in Applicants' paper filed 18 December 2009.

In response to the rejection of claim 36 (and claims depending therefrom) under 35 U.S.C. § 112, traversed *infra*, alleging that the limitation that the amount of active ingredient be 5% - 60% when the active ingredient is other than a retinoid *or* the amount of active ingredient is 1% - 20% when the active ingredient is a retinoid, Applicants have apportioned the subject matter of claim 36, and claims depending therefrom, over four groups of claims (37 - 50, 51 - 68, 69 - 85, and 86 - 92).

Two groups of claims (37 - 50 and 86 - 92) are drawn to a pharmaceutical and/or cosmetic product that does not include a retinoid. Two groups of claims (51 - 68 and 69 - 85) are drawn to a pharmaceutical and/or cosmetic product in which at least one ingredient is a retinoid. The subject matter of dependent claims 3 - 14, 16 - 26, and 31 -

35, now cancelled, is apportioned to each group of claims according to the relationship of their subject matter to the subject matter of new independent claims 37, 51, 69, and 86.

Applicants respectfully submit that support for the important limitation to "substantially the same lipophilicity" can be found, for example, in the claims as filed, and that support for the viscosity limitation common to all claims can be found at, for example, paragraph [0069] of the specification.

Applicants respectfully submit that support for the limitation to the amount of active ingredient other than a retinoid and the amount of active ingredient that is a retinoid can be found in the amendments to the specification at paragraphs [0054] to [0055] made in the paper filed 18 December 2009 in which Applicants amended their specification to expressly recite subject matter that had been properly incorporated by reference.

Applicants further respectfully submit that the new claims do not introduce new matter into the Application.

Claim Fees

By the present amendments, the Application now contains one (1) independent claim in excess of three and 35 total claims in excess of twenty. Applicants have previously paid for no independent claims in excess of three and 32 total claims.

The claim fees of $ 734.00 for one independent claim in excess of three and 24 claims in excess of 32 previously paid for are paid herewith by credit card.

Claim Rejections Under 35 U.S.C. § 112

Claims 3 - 14, 16 - 26, and 31 - 36 were rejected under 35 U.S.C. § 112, ¶1, because, it is alleged, claims to a product meeting the limitation "wherein the polymeric delivery system comprises about 5% to about 60% by weight of active ingredient, with the proviso that the active ingredient is not a retinoid, and comprises about 1% to about 20% when the active ingredient is a retinoid" lack written description in the specification. Applicants respectfully traverse.

By paper filed 18 December 2009, Applicants amended their specification thus:

> Between paragraphs [0054] and [0055], please insert the following two paragraphs.
>
> Generally speaking, it has been found that it is preferable for the bead to have a diameter from about 10 microns to about 100 microns, and have a calculated cross-linking in excess of about 10%. The active ingredient should comprise between approximately 5% to approximately 60% of the total weight of the composition or delivery vehicle comprising the polymeric bead and the active ingredient.
>
> When a retinoid is the active ingredient the retinoid impregnant, whether it be pure (solid) active ingredient, a mixture of active ingredients or a solution of active ingredient, will generally comprise between approximately 1% and approximately 20% of the total weight of the impregnated beads, usually being from about 1% to 2.5% of the total weight.

The quoted material was present in issued United States patents that were properly incorporated by reference in Applicants' specification.

Applicants recognized and disclosed (by reference) that retinoids were subject to different limits on amounts than were other active ingredients, and properly claimed their inventive product in the alternative; embodiments that that do not include an active ingredient that is a retinoid, or those that do, each embodiment subject to different limitations of the amount of active ingredient. The fact that traditional "Markush" language may not have been used is not relevant.

Without acquiescing to the grounds of the rejection, Applicants have apportioned the subject matter of the cancelled claims over 4 groups of claims: two groups drawn to a product that includes a retinoid, and two groups drawn to a product that does not include a retinoid. Applicants respectfully submit that, in view of the prior amendments to the specification, the new claims are free of any issue of written description that may have existed.

Claim Rejections Under 35 U.S.C. § 103

Claims 3 - 14, 16 - 26, and 31 - 35 were rejected as allegedly obvious over WO 01/912726 (WO '726) in view of US 7.060,732 to Vishnupad et al. (the '732 patent) and US 5,955,109 to Won et al. (the '109 patent), or in the alternative, as allegedly obvious over WO '726 in view of the '109 patent and EP 306236. Cancellation of the rejected claims moots the rejection. Applicants address the applicability *vel non* of the rejection to the new claims.

As an initial matter, Applicants recognize that the Office is charged with broadly construing claims under examination. But such broad construction must be reasonable and not contrary to law. See, e.g. *In re Baker Hughes, Inc.*, 55 USPQ 2d 1149 (Fed. Cir. 2000) (claim construction by the PTO is a matter of law reviewable *de novo*). *See also SRAM Corp. v. AD-II Engineering, Inc.*, 465 F.3d 1351 (Fed. Cir. 2006) (the PTO erred by impermissibly reading a limitation from the specification into a claim, violating a legal cannon of claim construction).

Applicants respectfully submit that it is settled law that all elements of a claim are material to defining the scope of a claim. *Warner-Jenkinson Co., Inc. v Hilton Davis Chemical Co.*, 550 U.S. 17, 41 USPQ2d 1865 (1997). When evaluating claims for obviousness under 35 U.S.C. 103, all words in a claim must be considered and given weight in judging the patentability of a claim over the prior art. M.P.E.P. § 2143.03. New claims 37 - 92 all expressly require that the water-based carrier bases of the separate first and second emulsion formulations must have substantially the same lipophilicity. Certain dependent claims recite maximum percentage difference in lipophilicities between water-based carriers.

Applicants respectfully submit that it is apparent on the face of the claims that the difference in lipophilicities referred to (more correctly, the lack of difference) relates to the difference in lipophilicities between separate and distinct water-based carriers of separate and distinct emulsion formulations that, prior to use, are stored in separate storage means, and does not relate to differences in lipophilicities between the components of the individual emulsion formulations.

WO '726 discloses a two precursor-component, acne-treating composition in which each precursor component is finished product (i.e., a formulation ready for use by the patient or consumer) stored in and dispensed from separate storage compartments

within a dispensing package. When dispensed, the component formulations are capable of forming the intended acne-treating pharmaceutical composition. *See* WO '726 at 23:1. The components include active ingredients. One component formulation can include an antibacterial such as BPO as an active ingredient. The other component formulation can include an antibiotic such as clindamycin as the active ingredient. The component formulations are stored separately because the stability of the individual formulations and the efficacy of the ultimate pharmaceutical composition may be compromised if they are stored together.

The only requirements for the component formulations in WO '726 are that they should not be too viscous to dispense and the final composition should adhere to the skin for sufficient time to be therapeutically effective. The component formulations that include the active ingredients can be gels, lotions, creams, salves, or ointments. Gels are particularly preferred. WO '726 at 23:10-12. WO '726 does not teach or suggest that the active ingredient can be imbibed in whole or in part in a polymeric delivery system (as that term is use in Applicants' claims), and more important, WO '726 is silent concerning any requirement for the lipophilicity of the component formulations.

The '732 patent discloses a "dual [chambered] dispenser" in which components of an acne-treating composition are separately stored. The '732 patent discloses that is strongly preferred that one of the components ("compositions") is substantially anhydrous. As far as Applicants are aware, the '732 patent does not disclose any embodiment in which at least one composition is not substantially anhydrous, and therefore, the '732 patent is not suggestive of an aqueous-based carrier.

More important, the '732 patent neither teaches nor suggests use of a polymeric delivery system (as that term is used in Applicants' claims) and the '732 patent is silent regarding the lipophilicity of the compositions used in the delivery systems therein disclosed.

The '109 patent discloses controlled release compositions for topical delivery of, *i.e.*, retinoic acid. In the controlled release compositions of the '109 patent, an active is retained in the pores of porous polymeric microbead carriers. These imbibed carriers can be used alone, or as a dispersion in a "suitable vehicle". '109 patent at 2:41-45. The '109 patent is silent concerning the lipohilicity of the "suitable vehicles" therein disclosed.

As Applicants have previously argued, the disclosure of EP '236 is at most cumulative.

Applicants' claims expressly require, *i.a.*, that the carriers of their first and second emulsion formulations have substantially the same lipophilicity. None of the art applied by the Office, alone or in any combination, teaches or suggests providing a topical formulation having two separate active ingredients, at least one of which is in a polymeric delivery system, contained in separate and separately stored delivery vehicles (e.g. emulsion formulations), in which the separate and separately stored delivery vehicles have substantially the same lipophilicity.

Accepting, *arguendo*, the Office's argument that, further in view of EP '236, it would have been obvious to use the microbead carriers of the '109 patent or EP '236 in the products disclosed in either or both of WO '726 or the '732 patent - a proposition to which Applicants have taken and, for reasons of record continue to take, vigorous exception - there is no teaching, suggestion, or motivation in the art applied by the Office to do what Applicants have done. And the Office's apparent attempt to rely on "common sense" in view of the knowledge in the art, allegedly evidenced by the '109 patent, amounts to impermissible *ex post facto* analysis and is, in any event, off the mark.

As Applicants best understand the Office's argument at page 9, bridging to page 10, of the final Office Action, the Office asserts that, if a formulation comprises a vehicle and suspended porous solid particles (or microspheres) that are impregnated with an active ingredient and an impregnating solvent, it would be obvious to use a vehicle that is immiscible with the impregnating solvent to minimize diffusion of the active ingredient (or its solution in the impregnating solvent) out of the porous solid particle. Even accepting this reasoning *in arguendo*, it is contrary to the disclosure of the '109 patent at 2:54 to 3:2, where it is taught that the active should diffuse, and, more important, it is irrelevant to the claim limitation at issue.

As discussed above, the "substantially the same lipohilicity" limitation relates to the lipophilicities of the individual carriers of the individual separately stored emulsion formulations. It is the lipophilicities of the "first" and "second" water-based carriers that must be substantially matched, **not** the lipophilicities of the components (e.g., vehicle and impregnating solvent) of the individual first and second emulsion formulations as discussed in the final Office Action.

For at least the foregoing reasons, Applicants respectfully submit that the rejection is not applicable to the new claims.

Applicants' Surrebuttal to the Examiner's Response to Applicants' Arguments

Applicants do not and have not argued against each of the combined references individually in traversing the rejections under 35 U.S.C. § 103, as implied at section 22 of the final Office Action. In *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), the Supreme Court confirmed that the *Graham* factors control the obvious analysis. The scope and content of the prior art is one of the *Graham* factors. Applicants are entitled to challenge, have challenged, and do challenge the Office's erroneous characterization of the scope and content of the prior art.

Conclusion:

Based on the foregoing amendments and remarks, Applicants respectfully submit that the claims are now in condition for allowance, which allowance is earnestly solicited. If, in the opinion of the Examiner, a telephone conference would advance prosecution of the Application, the Examiner is invited to telephone the undersigned attorney.

Date: September 13, 2010

Respectfully submitted,
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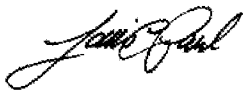

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